PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

	Date of mailing *(day/month/year)* 22.09.2004
Applicant's or agent's file reference JNR/P33144	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/12436	05.11.2003	07.11.2002

Applicant
GLAXO GROUP LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JNR/P33144	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/12436	International filing date *(day/month/year)* 05.11.2003	Priority date *(day/month/year)* 07.11.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant GLAXO GROUP LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07.05.2004	22.09.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Borowski, A Telephone No. +49 89 2399-2758

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/12436

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-20 as originally filed

Claims, Numbers

1-35 as originally filed

Drawings, Sheets

1/15-15/15 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 34-35

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 34-35

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	5,6,9-12,25-29
	No:	Claims	1-4,7-8,13-24,30-33
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-33
Industrial applicability (IA)	Yes:	Claims	1-33
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 34 and 35 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. Said claims contain references to the description and the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

   D1: EP-A-0 428 380 (RIKER LABORATORIES INC) 22 May 1991 (1991-05-22)
   D2: EP-A-0 075 548 (DRACO AB) 30 March 1983 (1983-03-30)
   D3: US-A-5 482 030 (KLEIN DAVID) 9 January 1996 (1996-01-09)

2. Claims 1-4, 7, 8, 13-24 and 30-33 do not contain any features which meet the requirements of the PCT (Article 33(2) PCT) in respect of novelty.

2.1 Independent claim 1 does not meet the requirements for novelty (Article 33(2) PCT), since it reads onto the disclosure of document D1, which is considered to represent the closest prior art for the present application (claims 1-21). Document D1 shows a drug delivery device for delivering to a patient a drug composition from a container which contains the drug composition (column 1, lines 1-12), the container adapted to be placed in a dispensing mode thereof on application of an actuating condition thereto, wherein the device comprises:
- a dispensing unit adapted to receive the container fig.4 (13)), the dispensing unit having an actuating mechanism operable to apply the actuating condition to the container and an outlet through which the drug composition is dispensable from the device (column 1, lines 42-45); and
- a removable casing unit for the dispensing unit (fig.4 (1)); and wherein:
- the dispensing and casing units have securing features for releasably, fixedly securing the units together (column 4, lines 28-42); and
- the dispensing unit is operable to apply the actuating condition to the container when fixedly secured to the casing unit (column 4, lines 15-27) and when

independent from the casing unit (column 2, lines 29-31).

2.2 All features of dependent claims 2-4, 7, 8 and 13-21 are also disclosed by document D1 - see especially column 3, line 30 - column 4, line 42.

2.3 Independent claim 22 does not meet the requirements for novelty (Article 33(2) PCT), since it reads onto the disclosure of document D2, which is considered to represent the closest prior art for the present application (claims 22-33). Document D2 shows a method of manufacturing a drug delivery device for delivery of a drug formulated in a drug container (page 1, paragraph 1) which is adapted to be placed in a dispensing mode on application of an actuating condition thereto, the method comprising the steps of:
- providing a dispensing unit (fig.1 (1)) for receiving the container (fig. 1 (3)) which has an actuating mechanism (fig.4 (5)) for applying the actuating condition thereto and an outlet (fig.4 (6)) through which the drug formulation is dispensed on application of the actuating condition to the container; and
- separately providing a casing unit (fig.1 (9)) adapted to fixedly hold the dispensing unit (fig.1 (1)) that the drug is dispensable from the container by the dispensing unit when held by the casing unit.

2.4 All features of dependent claims 23-24 and 30-33 are also disclosed by document D2 - see especially page 5, paragraph 2 - page 6, paragraph 1.

3. Claims 5-6, 9-12 and 25-29 of the present application do not meet the requirements for inventive step (Article 33(3) PCT).

3.1 The dispenser according to claims 5-6 differs from that known from document D1 only in that the features of cocking and breath activation have been omitted. Apart from the obviously and consequently simpler design of the device, the only result of the omission of said features is that the effect related to breath activation is no longer present in the dispenser according to claims 5 and 6. Such a simplification does not involve an inventive step (Article 33(3) PCT).

3.2 The subject-matter of claims 9-12 differs from the most relevant state of the art (document D1, see V.2.1) in that the container is fitted with a dose counter (claims 9-12). Same applies to the features of claims 25-29 in respect to document D2 (see V.2.3)

Problem to be solved by the differentiating feature may therefore be regarded as how to improve a patient compliance with prescribed medication dosing.

However, this feature has already been employed for the same purpose in a similar inhaler, see document D3, column 13, line 47 - column 14, line 47. It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply this feature with corresponding effect to a device according to document D1 (for claims 9-12) or respectively D2 (for claims 25-29), thereby arriving at a dispenser according to claims 9-12 (or respectively 25-29). The subject-matter of claims 9-12 and 25-29 does therefore not involve an inventive step (Article 33(3) PCT).

4. Independent claims 1 and 22 should have been drafted in the two-part form, as normally required by Rule 6.3(b) PCT.